Initial Approval: October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Rydapt® (midostaurin)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Midostaurin (Rydapt®)

CRITERIA FOR INITIAL APPROVAL (must meet all of the following):

- Patient must have one of the following:
  - Newly diagnosed with acute myeloid leukemia (AML) that is FLT3 mutation-positive, as detected by an FDA-approved test, and in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
  - Aggressive systemic mastocytosis (ASM)
  - Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
  - Mast cell leukemia (MCL)
- Patient must be 18 years of age or older
- Must be prescribed by or in consultation with an oncologist
- Patient must (one of the following):
  - Females: not be pregnant (verified negative pregnancy test within 7 days prior to initiating treatment for those of reproductive potential) or breastfeeding and be advised to not become pregnant or breastfeed for at least 4 months after the final dose
  - Males: advised to use effective contraception (e.g. condoms) during treatment and for at least 4 months after the final dose

LENGTH OF APPROVAL: 12 months

Notes:

- AML:
  - Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.
  - Newly diagnosed AML refers to those who are treatment naïve.
  - FLT3 has 2 subtypes of mutations: ITD, TKD. Information on FDA-approved tests for the detection of FLT3 mutation in AML is available at: http://www.fda.gov/CompanionDiagnostics.
  - Dosing: Rydapt 50 mg twice daily with food on Days 8-21 in combination with daunorubicin (60 mg/m2 daily on Days 1 to 3) /cytarabine (200 mg/m2 daily on Days 1 to 7) for up to two cycles of induction and high dose cytarabine (3 g/m2 every 12 hours on Days 1, 3 and 5) for up to four cycles of consolidation, followed by continuous Rydapt or placebo treatment according to initial assignment for up to 12 additional 28-day cycles.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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